

Legislation endorsed by: Consumers Union, National Consumers League, National Research Center for Women & Families, Partnership for Safe Medicines, Pew Prescription Project of Pew Charitable Trusts, U.S. Public Interest Group (PIRG)

***Legislation endorsed by: Consumers Union, National Consumers League, National Research Center for Women & Families, Partnership for Safe Medicines, Pew Prescription Project of Pew Charitable Trusts, U.S. Public Interest Group (PIRG)***

Washington, DC – On Wednesday, Rep. Steve Israel (D – N.Y.) announced endorsements from six top national consumer groups supporting the Congressman’s Counterfeit Drug Enforcement Act of 2009, also known as Tim Fagan’s law. The legislation expands FDA authority to combat the distribution and sale of dangerous counterfeit medications.

“Consumers have a right to trust the products their doctors say will make them better. This year alone, an estimated 35 million prescriptions will be filled with counterfeit medicine. My legislation will empower the FDA to crack down on counterfeiting and increase the criminal penalties for the outlaws who are compromising our health,” said Rep. Israel. “This will be a tough fight, and I’m proud to have the nation’s top consumer and public health advocates as partners pushing with me to ensure that the domestic drug supply chain is secure for every American.”

In letters of endorsement, consumer groups praised the protections in Rep. Israel’s bill:

**Consumers Union:** “We strongly endorse [Rep. Israel’s] efforts to strengthen the laws against prescription drug counterfeiting, and we hope that the type of consumer protections included in [Rep. Israel’s] bill can become part of this year’s health reform legislation or part of the food and drug safety legislation moving separately.”

**Pew Prescription Project:** “We fully support [Rep. Israel’s] efforts to reform the U.S. pharmaceutical and medical device distribution supply chain to protect consumers against counterfeit and adulterated products. While the vast majority of pharmaceutical products sold in the United States are not adulterated, recent events demonstrate the unacceptable and sometimes deadly consequences for consumers when we fail to ensure the integrity of manufacturing and distribution.”

**National Research Center for Women & Families:** “The Food and Drug Administration estimates that about one percent of our prescription drug supply is counterfeit. That may seem like a minuscule amount, but it is 35 million prescriptions including medications to treat heart disease, diabetes and cancer. Counterfeit drugs makers endanger patients’ lives, and they steal billions of dollars from consumers and government programs such as Medicare and Medicaid. ‘Tim Fagan’s Law’ will increase criminal penalties—up to life in prison—for selling counterfeit prescription drugs, require a chain of custody for a drug from manufacturer to wholesaler to pharmacist, and require drug companies to use anti-counterfeiting technology. The bill will also empower the FDA with new recall and subpoena authorities so that the Agency can more effectively respond to suspected counterfeit drugs.”

**U.S. PIRG:** “U.S. PIRG strongly supports [Rep. Israel’s] proposed bill H.R. 2726, The Counterfeit Drug Enforcement Act of 2009. Too often today, consumers are left in the dark as to the safety, purity and even the nature of the drugs they are taking. Unless we are to continue to place American lives at risk, Congress must address this serious issue. Your bill would do exactly that...”

**Partnership for Safe Medicines:** “We would like to commend [Rep. Israel’s] leadership in introducing H.R. 2726, the Counterfeit Drug Enforcement Act of 2009. Protecting American’s from the dangers of counterfeit drugs is urgently needed as counterfeit drugs impact virtually every country in the world and virtually every disease state. Safety must be our top national priority as health reform advances and access to care extends to some of our most vulnerable patient populations.”

**National Consumers League:** “Since our founding more than a century ago, the National Consumers League has been a champion of efforts to protect the integrity of the nation’s drug supply... We strongly believe that all Americans should have access to safe, effective, and affordably priced prescription medications. We believe that HR 2726 would help address this issue by giving the FDA additional authority to fight the proliferation of harmful counterfeit medications. In particular, we support the adoption of technologies to improve medication tracking processes, particularly those that address the problem of counterfeit drugs.”

The legislation is named for one of Rep. Israel’s constituents, Tim Fagan, who received counterfeit medication in place of the prescription he needed following a liver transplant. The injections he received only had a small amount of the medicine he actually required and wreaked havoc on Tim.

Counterfeit drugs are defined as those without the active ingredient, with an insufficient or excessive quantity of the active ingredient, with the wrong active ingredient, or with fake packaging. The World Health Organization estimates counterfeit drugs are a \$35 to \$40 billion a year industry.

Tim Fagan’s Law to combat counterfeit drugs will:

- Give the FDA recall authority, the same way the FDA can recall faulty medical equipment;
- Increase criminal penalties for counterfeiting;
- Mandate that drug manufacturers alert the FDA in 2 days when they learn that one of their drugs has been counterfeited;
- Authorize funds specifically for spot-checking (\$300 million over 5 years);
- Provide the FDA with the authority to require companies to use anti-counterfeiting technology;
- Require the FDA to remove the stay placed on paper pedigree requirements, which were mandated in the Prescription Drug Marketing Act of 1988;
- Authorize \$5 million for each year between fiscal years 2010 and 2014 for educating the public and health care professionals on how to identify counterfeit drugs; and

- Authorize the FDA to issue subpoenas with respect to preventing threats to public health.

Rep. Israel has led the charge against counterfeit drugs for the last seven years. His efforts are documented as part of the book *Dangerous Doses* by Katherine Eban.

Rep. Israel serves on the House Appropriations Committee.